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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER LOPEZ, CARLOS N	
			ART UNIT 1791	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/623,006

Applicant(s)

KRUKONIS ET AL.

Examiner

CARLOS LOPEZ

Art Unit

1791

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16, 18 and 20-37 is/are rejected.
- 7) ☒ Claim(s) 14, 15, 17, 19 and 38-43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Objections

Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 29 fails to further limit claims 1, 3, and 5 because said claims already provide a tobacco with a moisture content of at least 10%.

Claim 30 is objected to because of the following informalities: typing error of the word "or" at the first line of claim 30. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 25-27, the phrase "said tobacco" makes it unclear to which tobacco is being referred. Is it the tobacco of step a, b, or c?

It is noted for the record that the phrase "or wherein said tobacco having a reduced amount of ..." in claims 1, 3, and 5 is being read as an optional limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4, 8-10, 12-13, 16, 18, 20-21, 23-24, 28, and 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller (US 4,506,682). Muller discloses providing a vessel 4 comprising tobacco (see Abstract), contacting the tobacco with sub-critical carbon dioxide (see Col. 3, lines 8ff), and removing the fluid from the vessel to extract a component (tobacco aroma oil) from the tobacco (see abstract).

As for claims 2 and 4, each specifying a component of the extracted material, it is deemed that, in view of Muller contacts the tobacco under the substantially the same sub-critical conditions (See Muller Col. 3-4) as disclosed by applicant such as temperature range, pressure range, ratio of carbon dioxide to tobacco, and treatment time, it would be inherent that the claimed specific components would also be extract from Muller's treated tobacco.

As for claims 8-10, the fluid contacting the tobacco is described by Muller as being a gas and a liquid (Col. 7, lines 32).

As for claims 12-13, the sub-critical fluid comprising tobacco components are separated by a heat-exchanger and expansion vessel 10. (See Col. 7, lines 39ff) The component, tobacco aroma oil, would comprise of the claimed PAH in view that it is obtained by similar process conditions set forth by applicant's specification.

As for claims 16, and 18, 20-21, separator vessel is deemed as heat exchanger 9 wherein the substance capable of separating the constituent tobacco oil is deemed as the cooling fluid of the heat exchanger wherein the temperature of the sub-critical is

lowered to in order to precipitate the constituent dissolved in the sub-critical fluid (See Col 7, lines 37ff).

As for claims 23-24, the sub-critical fluid is re-circulated back to the vessel 10, deemed as the vessel used in step B of applicant's claims. (See Col.7, lines 47ff)

As for claim 28, see above.

As for claims 34 and 36, see above

Claims 1, 3, 11, 29, 30-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by White (US 6,048,404). White discloses at Col. 3, lines 50-53 discloses treating tobacco in a Parr bomb (the claimed vessel). The tobacco in the vessel contains 10% moisture content, see example 1. The vessel is filled with ethane as noted in Col. 5, lines 41 and the tobacco is contacted with the carbon dioxide at sub-critical conditions, see Col. 3, lines 38-58 providing temperature and pressure that are sub-critical. The sub-critical fluid would be removed when the Parr bomb is opened to remove the tobacco. In regards to the claimed reduction of constituent tobacco, it would be inherent that the tobacco will have a reduced constituent as claimed because White contacts the tobacco under the substantially the same sub-critical conditions as claimed by applicant.

As for claim 30, the pH of untreated tobacco is in the claimed range of 4-9.

As for claims 33 and 35, in view that the process limitations are met by White, the product derived from the claimed process would be inherently the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller (US 4,506,682). Mueller teaches the claimed process steps except for treating of the tobacco having a10% moisture. However, it is deemed that the claimed product would have been obvious to a person of ordinary skill in the art because Mueller substantially mirrors the claimed process steps.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In the instant case the claimed process only differs from Mueller in that it recites a specific moisture content of the treated tobacco. However, it is deemed that said limitation does not further add structural limitations distinct to Mueller's tobacco because it would be expected to have the claimed reduction of constituent tobacco would also be share by Mueller in view that the process steps of Mueller and the claimed invention are substantially the same.

Claims 5-7 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 6,048,404). As for claims 5-7 and 22, White does not disclose the reuse of the gas filling the Parr bomb but it would have been obvious to a person of ordinary skill in the art to have recycled the gas in order to reduce cost. Furthermore, it would have been obvious to a person of ordinary skill in the art to have the gas that previously filled the Parr bomb to be channeled into another vessel in order to prevent contamination of the atmosphere around the operators of the Parr bomb. Consequently in re-using the gas, a vessel in connection with the Parr bomb would be required in order to remove the gas filling the Parr bomb. Additionally, the Parr bomb would be isolated from the vessel/ Parr bomb receiving the gas that filled the Parr bomb in order to allow for the tobacco to be removed from the Parr bomb after the tobacco has been treated.

Allowable Subject Matter

Claims 14, 15, 17, 19 and 38-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 5/26/09 have been fully considered but they are not persuasive. In regards to the 112 2nd paragraph rejection, applicant fails to specifically provide which tobacco is being referred to in claims 25-27. Applicant summarizes what the claims provide but such showing does not clarify in the claim which tobacco is being deposited with the removed components of step b.

Applicant argues that claims 2 and 4 are not disclosed by the prior art because "the methods cannot result in selective removal of PAH or secondary alkaloid."

As noted above, it was deemed that, in view of Muller contacts the tobacco under the substantially the same sub-critical conditions (See Muller Col. 3-4) as disclosed by applicant such as temperature range, pressure range, ratio of carbon dioxide to tobacco, and treatment time, it would be inherent that the claimed specific components would also be extract from Muller's treated tobacco. Furthermore, the claim does not require any degree of specificity, meaning the process of claims 2 and 4 does not require that only PAH or secondary alkaloid be removed. Hence, in view that Applicant has not addressed the Examiner's prima facie reasoning noted above, Applicant's argument is deemed as unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARLOS LOPEZ whose telephone number is (571)272-1193. The examiner can normally be reached on Mon.-Fri. 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571.272.1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos Lopez/
Primary Examiner
Art Unit 1791